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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,418	07/23/2003	Kevin T. Foley	4002-3363/PC459.06	8146

52196 7590 06/01/2006

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EXAMINER

REIMERS, ANNETTE R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,418	FOLEY ET AL.	
	Examiner	Art Unit	
	Annette R. Reimers	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-17, 20 and 21 is/are rejected.
- 7) ☒ Claim(s) 8, 18 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Zucherman et al. (U.S. Patent Number 5,700,264).

Zucherman et al. disclose a method for preparing a spinal disc space, comprising inserting a body portion of a distractor, 65, into the spinal disc space with an upper surface of the body portion adjacent an endplate of an upper vertebra and a lower surface of the body portion adjacent an endplate of a lower vertebra, advancing a cutting instrument, 34, over the body portion, and a cavity, 64, capable of receiving cut material, is formed in the body portion, the cavity opening toward each of the upper and lower surfaces (see column 4, lines 61-64). Insertion of the body portion includes contacting the endplate of the upper and lower vertebrae with the adjacent one of the upper and lower surfaces of the body portion. The cutting instrument and the body portion are removed from the disc space and an implant is inserted into the spinal disc space (see figures 8 and 11 and column 4, lines 36-65). Zucherman et al. teaches the use of imaging techniques to navigate the instrument (see column 4, lines 28-31).

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Claims 16-17 and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilhelmy (U.S. Patent Number 5,722,977).

Wilhelmy discloses a method for preparing a spinal disc space, comprising inserting a body portion of a distractor, 15, into the spinal disc space, advancing a cutting instrument, 7, over the body portion into the spinal disc space, and limiting advancement of the cutting instrument into the spinal disc space by contacting the cutting instrument with a distal end wall of the body portion. The distal end wall includes a first width, and the cutting instrument includes an elongated shaft having a distal cutting end, the distal cutting end of the shaft configured to interfit with the body portion and includes a distally opening channel to receive the body portion of the distractor, the distal cutting end including a second width that is less than the first width. Insertion of the body portion includes contacting the endplate of the upper and lower vertebrae with the adjacent one of the upper and lower surfaces of the body portion. The cutting instrument and the body portion are removed from the disc space, and an implant is inserted into the spinal disc space (see figures 14-18, column 5, lines 13-24 and column 8, lines 3-25).

Claims 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Levine (U.S. Patent Number 5,423,825).

Levine discloses a method for preparation of a disc space between adjacent vertebrae, comprising a distractor insertable into the disc space, the distractor includes a body portion, 19, extending between a leading end and a trailing end, the distractor further including a flange, 53, extending from the leading end towards the trailing end of

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the body portion, the flange forms a slot, 21, along the body portion, and provides a cutting instrument, 45, advanceable over the body portion from the trailing end and into the slot formed between the body portion and the flange of the distractor (see Figure 1).

The cutting instrument is adapted to cut bony material from vertebral endplates adjacent the disc space to form an implant insertion location in the disc space. Furthermore, the cutting instrument defines a channel, 111, sized to receive the body portion of the distractor. In addition, the body portion includes a cavity, 55, capable of receiving at least a portion of the cut bony material (see figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilhelmy (U.S. Patent Number 5,722,977) in view of Hanson et al. (U.S. Patent Number 6,641,582).

Wilhelmy discloses a method for preparing a spinal disc space, comprising inserting a body portion of a distractor, 15, into the spinal disc space with an upper surface of the body portion adjacent an endplate of an upper vertebra and a lower surface of the body portion adjacent an endplate of a lower vertebra, advancing a cutting instrument, 7, over the body portion to remove material between the upper and lower surfaces of the body portion and the adjacent vertebra (see figures 14-18).

The cutting instrument is advanced over the body portion to remove material between the upper and lower surfaces of the body portion and each of the adjacent vertebra, and the cavity of the body portion is capable of receiving cut material. Insertion the body portion includes contacting the endplate of the upper and lower vertebrae with the adjacent one of the upper and lower surfaces of the body portion. Advancement of the cutting instrument includes contacting a distal end of the body portion to limit advancement of the cutting instrument into the disc space. The cutting instrument and the body portion are removed from the disc space and an implant is inserted into the spinal disc space (see figures 14-18, column 5, lines 13-24 and column 8, lines 3-25).

Wilhelmy discloses the claimed invention except depositing cut material into a cavity formed in the body portion, wherein the cavity opens toward each of the upper and lower surfaces. Hanson et al. disclose depositing cut material into a cavity 24 formed in the body portion 25, wherein the cavity opens toward each of the upper and lower surfaces and teaches the use of the cavity for passage of bone debris collected within the cavity during cutting (see column 5, lines 37-39). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Wilhelmy having a cavity formed in the body portion for depositing cut material, wherein the cavity opens toward each of the upper and lower surfaces, in view of Hanson et al., in order to provide a cavity for passage of bone debris collected within the cavity during cutting.

Allowable Subject Matter

Claims 8, 18, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed on February 10, 2006 have been fully considered, but they are not persuasive. Regarding Zuckerman et al., examiner respectfully disagrees with applicant, since bone material can be deposited into bore 64 (see column 4, lines 61-64). Since bone and disk tissue is captured between probe 22 and cutter 34, it is possible that bore 64 can contain bone and disk tissue, even though it is occupied by post 26.

Examiner respectfully disagrees with applicant regarding the Wilhelmy reference. Examiner considers 27 to be the distal end wall of the body portion, which includes a first width that is greater than the width of the distal cutting end 43 (see figure 18 and column 8, lines 5-8).

Examiner respectfully disagrees with applicant regarding the Levine reference. Trailing end and leading end are relative terms. Therefore, either end can be considered the trailing end. Thus, it is a matter of interpretation, and examiner has interpreted the cutting instrument to be advanceable over the body portion from the trailing end not the leading end.

Examiner respectfully disagrees with applicant regarding Wilhelmy in view of Hanson et al. The element of the method that is lacking in Wilhelmy is depositing cut

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material into a cavity formed in the body portion, wherein the cavity opens toward each of the upper and lower surfaces. As stated above, Hansen et al. disclose depositing cut material into a cavity 24 formed in the body portion 25, wherein the cavity opens toward each of the upper and lower surfaces and teaches the use of the cavity for passage of bone debris collected within the cavity during cutting (see column 5, lines 37-39). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Wilhelmy having a cavity formed in the body portion for depositing cut material, wherein the cavity opens toward each of the upper and lower surfaces, in view of Hansen et al., in order to provide a cavity for passage of bone debris collected within the cavity during cutting.

Examiner also respectfully disagrees with applicant that a modification of Wilhelmy would result in the cutting instrument being provided with openings to deposit cut bone material. As previously stated, Hansen et al. disclose depositing cut material into a cavity 24 formed in the body portion 25, wherein the cavity opens toward each of the upper and lower surfaces and teaches the use of the cavity for passage of bone debris collected within the cavity during cutting (see column 5, lines 37-39).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not


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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER